A.1b—A list of all required assurances that must be submitted with the plan;

A.1c—Copies of all certifications that are to be complied with and clarification about which one will have to be signed and actually submitted with the plan.

Attachment A.2 presents the statutory basis for five-year plan approval.

Attachment A.3 presents the statutory basis for exempting eligible Indian Tribes from inappropriate requirements.

★ Attachment B addresses the new CFS–101, which consists of the State Annual Budget Requests for title IV–B, subparts 1 and 2, and the State annual Summary of Child Welfare Services. The new CFS–102 is essentially an updated CWS–101 and requests some new information so States can receive their subpart 2 allotment:

Attachment B.1 provides a general orientation to the new CFS–101. Included in Attachment B.1 are:

B.1a—Information on the development of the CFS–101;

B.1b–General directions and timeframes for submission of the CFS–101.

Attachment B.2 provides instructions for filling out the three forms which constitute the CFS–101:

(Form 1) Part I: Annual Budget Request for Title IV–B, Subpart 1, Child Welfare Services. Part I is the same as the old CWS–101 Part I: Annual Budget Request;

(Form 2) Part I Supplement: Annual Budget Request for Title IV–B, Subpart 2. Part I Supplement is a new form for States to request funds from the Family Preservation and Support Services Program;

(Form 3) Part II: Annual Summary of Child and Family Services. Part II is essentially the same as the old CWS–101 Part II, except that some new information relevant to implementation of the Family Preservation and Support Services Program is being requested

Copies of all the forms are enclosed.

Submittals: The Five-Year Plan

An original and two copies of the plan must be submitted to the Administration for Children and Families (ACF) Federal Regional Office by June 30, 1995. Guidelines can be found in Attachment A.

The CFS–101

The due dates for the Annual Budget Requests and the Annual Summary of Services for FYs 1995 and 1996 vary depending upon a number of different circumstances. Explicit instructions can be found in Attachment B.

Submit the original (with original signature) and two copies to the Administration for Children and Families (ACF) Federal Regional Office.

[FR Doc. 95–11825 Filed 5–12–95; 8:45 am]

BILLING CODE 4184–01–M

Agency Information Collection Under OMB Review

Title: ACF—535 LIHEAP Quarterly Estimates

OMB No.: 0970–0037

Description: The information collected is used to develop our apportionment request for appropriated Low-Income Home Energy Assistance Programs (LIHEAP) funds and to make grant awards based on the funding needs of States and Tribes.

Respondents: State and tribal governments

Annual Number of Respondents: 55 sites

Number of responses per respondent: 1

Total annual responses: 55 sites

Hours per response: .25

Total Annual Burden Hours: 14

Additional Information: Copies of the request for approval may be obtained from Bob Sargis of the Office of Information Resource Management, ACF, by calling (202) 690–7275.

OMB Comment: Consideration will be given to comments and suggestions received within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: May 8, 1995.

Roberta Katson,

Acting Director, Office of Information Resource Management.

[FR Doc. 95–11826 Filed 5–12–95; 8:45 am]

BILLING CODE 4184–01–M

Food and Drug Administration

[Docket No. 95N–0109]

Animal Drug Export; Marbofloxacin

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Pfizer, Inc., has filed an application requesting approval for the export of a specific amount of the bulk form of the new drug substance marbofloxacin to France.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of animal drugs under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: Gregory S. Gates, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1617.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the export of drugs that are not currently approved in the United States. Section 802(b)(3)(B) of the act sets forth the requirements that must be met in an application for approval. Section 802(b)(3)(C) of the act requires that the agency review the application within 30 days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802 (b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Pfizer, Inc., 235 East 42d St., New York, NY 10017, has filed application number 6936 requesting approval for the export of a specific amount of the bulk form of the new drug substance marbofloxacin to France for further manufacture of the finished dosage form Marbocyl, 5 milligram Tablets (antimicrobial for treatment of dogs and cats). The tablets will then be shipped to the United Kingdom where they are approved for marketing. The application was received and filed in the Center for Veterinary Medicine on April 24, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by May 25, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Veterinary Medicine D(21 CFR 5.44).

Dated: May 5, 1995.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 95–11930 Filed 5–12–95; 8:45 am]

BILLING CODE 4160–01–F

Product and Establishment License Applications, Refusal To File; Establishment of Refusal to File Oversight Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a standing oversight committee in the Center for Biologics Evaluation and Research (CBER) to conduct periodic reviews of CBER's use of its refusal to file (RTF) practices on product license applications (PLA's) and establishment license applications (ELA's). CBER's RTF oversight committee will examine RTF decisions to assess consistency across CBER offices and divisions in RTF decisions and to determine whether the guidance currently available to sponsors needs to be revised.

ADDRESSES: Submit written requests for single copies of the CBER RTF guidance document to the Office of External Affairs, Industry Liaison Staff (HF–50), Food and Drug Administration, rm. 15–61, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jean M. Olson, Center for Biologics Evaluation and Research (HFM–635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–594–3074.

SUPPLEMENTARY INFORMATION: The importance to the public health of getting new biological products on the market as efficiently as possible has made improving the biological product evaluation process an FDA priority, as evidenced by initiatives, such as the following: (1) Procedures to expedite marketing approval for therapies for serious or life threatening illnesses (53 FR 41516, October 21, 1988; 57 FR 58942, December 11, 1992); (2) procedures and policies to make such therapies available prior to marketing approval through mechanisms such as the treatment investigational new drug (52 FR 19466, May 22, 1987) and the parallel track (57 FR 13250, April 15, 1992); (3) announcement of the availability of a CBER RTF guidance document for sponsors (58 FR 38770, July 20, 1993); and (4) implementation of a managed review process for PLA's, ELA's, and supplements to PLA's and ELA's. The managed review process focuses on specific milestones or intermediate goals so that a quality review is conducted within specified time periods. The establishment and first meeting of CBER's RTF oversight committee, announced and described in this notice, continue CBER's effort to promote the timely, efficient, and consistent review of PLA's and ELA's.

CBER recognizes that the practice of submitting incomplete or inadequate PLA's and ELA's and then providing additional information to FDA during an extended review period is inherently inefficient and wasteful of FDA resources. Such practice is also unfair to those sponsors who fulfill their scientific and legal obligations by submitting complete applications; the review of complete applications may be delayed while incomplete applications, submitted earlier, undergo review and repair.

By means of an RTF notification, CBER in general declines to file a sponsor's PLA or ELA because of omissions or inadequacies so severe as to render the application incomplete on its face. Although not a final determination, an RTF decision is a significant step that delays, at least for a time, full review of an application. CBER believes that an RTF decision is, in general, of benefit to sponsors as an early signal that the application has major deficiencies.

FDA regulations on filing PLA's and ELA's are found in §§ 601.2(a) and 601.3 (21 CFR 601.2(a) and 601.3). A sponsor who receives an RTF notification may request an informal conference with CBER, and thereafter the sponsor may ask that the application be filed over protest, similar to the procedure for drugs described under § 314.101(a)(3) (21 CFR 314.101(a)(3) (see 57 FR 17950, April 28, 1992).

CBER has formed a standing RTF oversight committee, consisting of senior CBER officials, a senior official from FDA's Center for Drug Evaluation and Research, and FDA's Chief Mediator and Ombudsman. Meetings will be held once a quarter to review all of the RTF decisions. The purpose of such a review is to assess the consistency within CBER in rendering RTF decisions and to determine whether the currently available guidance provided to sponsors needs to be revised or supplemented.

Because the committee's deliberations will deal with confidential commercial information, all meetings will be closed to the public. The committee's deliberations will be reported in the minutes of the meeting. Although those minutes will not be publicly available because they will contain confidential commercial information, summaries of the committee's deliberations, with all such confidential commercial information omitted, will be available from the FDA Chief Mediator and Ombudsman. If, following the committee's review, an RTF decision changes, the reviewing division will notify the sponsor of the change.

Dated: May 5, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–11827 Filed 5–12–95; 8:45 am]

BILLING CODE 4160–01–F

International Scientific Conference on Viral Safety and Evaluation of Viral Clearance From Biopharmaceutical Products; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), is announcing a meeting to discuss viral safety of biopharmaceutical products. FDA is cosponsoring the meeting with the National Institute of Allergy and Infectious Diseases (NIAID), the U.S. Department of Agriculture (USDA), the National Vaccine Program Office (NVPO), and the International Association of Biological Standardization (IABS). The meeting is intended to provide an exchange of information related to the viral safety of biological products, including information relevant to an International Conference on Harmonization (ICH) guideline on viral testing and validation that is presently under development.

DATES: The public meeting will be held on June 14 and 15, l995, from 8:30 a.m. to 5 p.m., and on June 16, 1995, from 8:30 a.m. to 3:30 p.m. Participants may pick up their information packages and badges for admission to the sessions beginning at approximately 7:30 a.m. each morning.

ADDRESSES: The public meeting will be held at the National Institutes of Health, Bldg. 45, Main Auditorium of the Natcher Conference Center, 9000 Rockville Pike, Bethesda, MD. There is no registration fee for this meeting. Space is limited, and all interested parties are encouraged to register early (see the contact person listed below).

FOR FURTHER INFORMATION CONTACT:

For information regarding registration, housing, and other arrangements: Tammy Lowry, KRA Corp., 1010 Wayne